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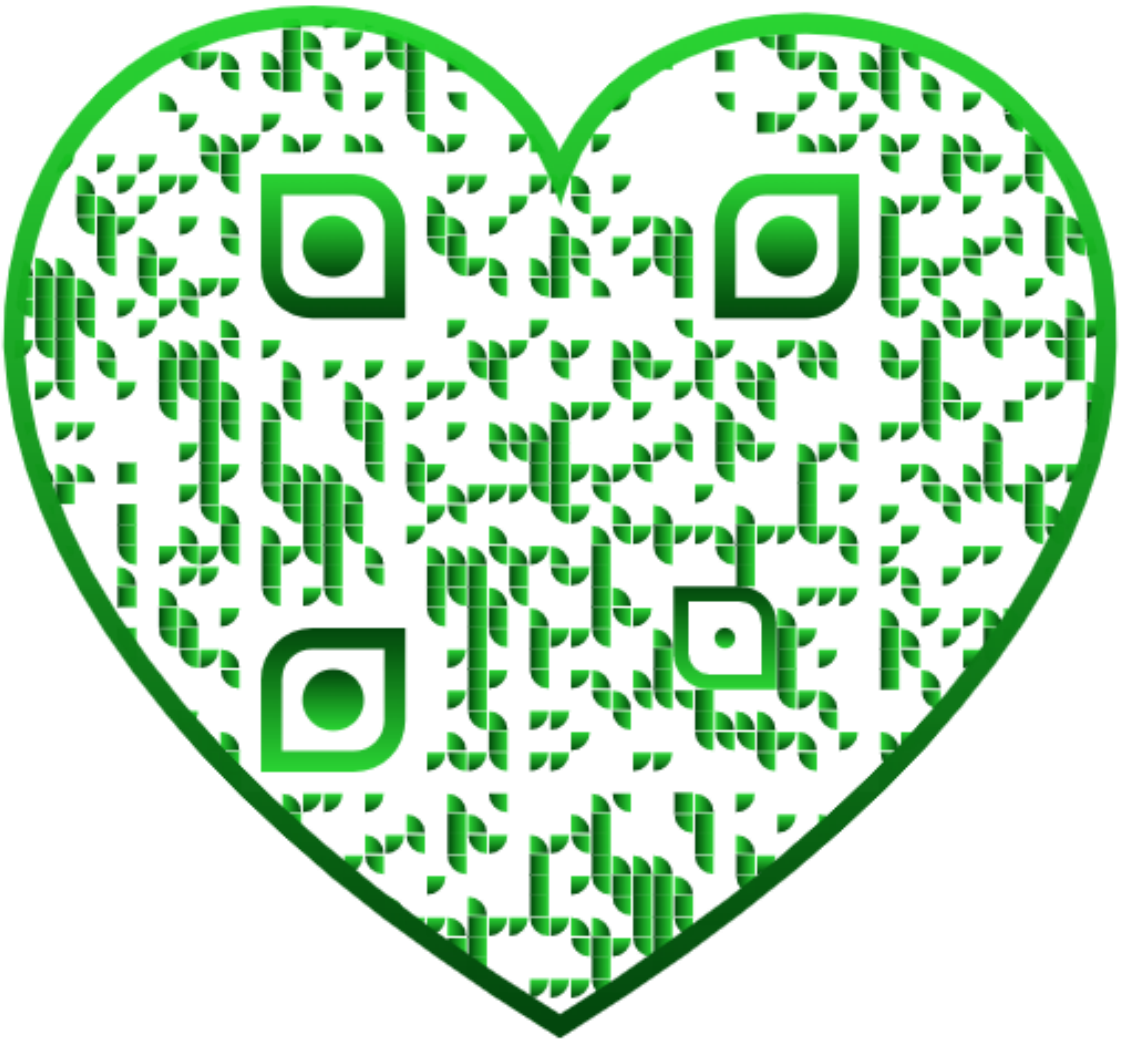
Pharmaceutical Services Programme

Ministry of Health Malaysia

GUIDELINE ON SAFE USE OF HIGH ALERT MEDICATIONS (HAMs)

2nd Edition



GUIDELINE ON SAFE USE OF HIGH ALERT MEDICATIONS (HAMs)

Second Edition

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Summary	High Alert Medications (HAMs) are medications that bear a heightened risk of causing significant patient harm when these medications are used in error. This guideline outlines the safe use of high alert medications and recommend the risk prevention strategies that can be implemented by health care providers on the management of high alert medications at all stages.
Replaces Document	Guideline on Safe Use of High Alert Medications First Edition 2011
Author	Medication Safety Section Pharmacy Practice and Development Division Pharmaceutical Services Programme Ministry of Health Malaysia
Applies to	All government healthcare facilities
Audience	Healthcare professionals
Review Date	November 2025

FOREWORD

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In the last decade, the role of pharmacists in ensuring patient safety during health services delivery has evolved considerably and significant portions of the Program's work have been delivered. As we embark into the years 2021 – 2025, the Pharmaceutical Services Programme continues to strive towards developing a strong and resilient people-centred health system with primary care as foundation, integrating patient safety and medication safety across all levels of care, within the context of universal health coverage.

Having identified high-risk situations, transitions of care and polypharmacy as three priority areas to protect patients from harm, in March 2017, the World Health Organization (WHO) launched the third *Global Patient Safety Challenge: Medication Without Harm* with goal of reducing severe, avoidable medication-related harm by 50%, over the next 5 years. This guideline on Safe Use of High Alert Medications aims to strengthen national efforts as part of the strategic agenda of the Pharmaceutical Services Programme towards improving patient safety.

Medication safety is a continual learning process and requires commitment and perseverance from all stakeholders. It must be an integral part of the education and training of inter-professionals to avoid clinical errors and make health care safer for all patients, everywhere, every time.

Patient Safety, Our National Health Priority.

ACKNOWLEDGEMENT

First and foremost, we would like to express our sincere gratitude to the authors and individuals who are involved directly or indirectly for their valuable and constructive comments in the establishment of this guideline.

We are immensely grateful to all Medication Safety Liaison Officers at the state level for their support and efforts towards promoting and improving medication safety practices in the hospitals and health clinics.

We would also like to extend our appreciation to all healthcare personnel for their commitment, teamwork, and initiatives in ensuring safe medication practice.

Last but not least, we would like to acknowledge and thank all healthcare professionals for their constant reporting on medication errors and every effort to prevent medication errors in their facilities.

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HIGH ALERT MEDICATIONS (HAMs)

PURPOSE

i. To assist healthcare professionals in identifying high alert medications.

ii. To establish safeguards to reduce avoidable harm and the risk of errors with high alert medications in healthcare facilities.

iii. To accelerate the implementation of safe preventive strategies in all stages of the medication use process.

iv. To increase awareness of healthcare professional on the importance of counterchecking in safe handling of high alert medications.

INTRODUCTION

High alert medications (HAMs) are defined as medications that bear a heightened risk of causing significant patient harm when these medications are used in error. HAMs or high-risk medications, in the context of safe use relating to certain situations, are associated with a significant risk of harm. Though medication mishaps with high alert medications may or may not be more common than other medications, the consequences following an error with these medications can be serious to the patient. The inherent risk of using HAMs, work environment (e.g. in the case of hospital inpatient settings), organizational culture and clinical scenarios (e.g. emergency and anaesthesia settings) could impose difficulties for healthcare professionals in ensuring patient safety while delivering health services. Similarly, there are also some conditions inherent to vulnerable groups, such as pregnant women, children and elderly, and clinical risk areas such as cancer patients. These are just some examples of high-risk situations.

Following the recent launch of the Third Global Patient Safety Challenge: *Medication Without Harm* by the WHO, an international prioritization exercise involving experts from the WHO Global Patient Safety Network identified development of contextual guidelines and standard operating procedures, focused training courses for health care professionals and patient education, as well as score-based approaches to predict high-risk patients and situations to avoid medication related harm. While the medications identified in the list of HAMs may vary between health care settings based on the patient population treated and preferences of specific agent within a pharmacological class in different work environment, a specific high-risk medications list has been drawn up based on the reported cases submitted

to the national Medication Error Reporting System (MERS) of the Pharmaceutical Services Programme, Ministry of Health Malaysia.

HAMs, as a whole, warrant special safeguards during the process of health care to reduce the risk of unnecessary patient harm associated with adverse medication events such as the preventable medication errors. In the context of strategic framework of the challenge, it has been suggested that there are four domains that influence safe use of HAMs. These are:

- Patients and the public
- Healthcare professionals
- Medicines
- System and practices of medication

Fig. 1. Strategic Framework of the Global Patient Safety Challenge
Source: The Third WHO Global Patient Safety Challenge: Medication Without Harm.
Available at: https://www.who.int/patientsafety/medication-safety/en/

CATEGORIES OF HIGH ALERT MEDICATIONS

All medications categorized in **Table 1** are examples categories of High Alert Medications (HAMs) although it may not be listed individually in this guideline. The healthcare facilities should review the list and identify their own individual list of HAMs.

Table 1: Categories of High Alert Medications

1.	**Adrenergic agonists, IV** **(e.g. adrenaline, phenylephrine, noradrenaline)**
2.	**Adrenergic antagonists, IV** **(e.g. propranolol, labetalol)**
3.	**Anaesthetic agents, general, inhaled and IV** **(e.g. propofol, ketamine)**
4.	**Antiarrhythmics, IV** **(e.g. lignocaine (lidocaine), amiodarone)**
5.	**Antithrombotic agents** **(e.g. warfarin, heparin, enoxaparin, dabigatran, rivaroxaban, apixaban, fondaparinux, tirofiban, tenecteplase)**
6.	**Antivenom** **(e.g. sea snake, cobra, pit viper antivenom)**
7.	**Chemotherapeutic agents, parenteral and oral**
8.	**Epidural and intrathecal medications**
9.	**Glyceryl Trinitrate injection**
10.	**Immunosuppressant agents** **(e.g. azathioprine, cyclosporine, tacrolimus)**
11.	**Inotropic medications, IV** **(e.g. digoxin, dobutamine, dopamine)**
12.	**Insulin, subcutaneous and IV**
13.	**Magnesium sulfate injection**

14.	**Moderate and minimal sedation agents, oral, for children** **(e.g. chloral hydrate, midazolam, ketamine [using the parenteral form])**
15.	**Moderate sedation agents, IV** **(e.g. dexmedetomidine, midazolam, lorazepam)**
16.	**Neuromuscular blocking agents** **(e.g. pancuronium, atracurium, rocuronium, vecuronium)**
17.	**Opioids, including:** • **IV** • **oral (including liquid concentrates, immediate- and sustained-release formulations)** • **transdermal**
18.	**Oxytocin, IV**
19.	**Parenteral Nutrition preparations**
20.	**Potassium salt injections**
21.	**Sodium Chloride for injection, hypertonic (greater than 0.9% concentration)**
22.	**Dextrose, Hypertonic (20% or greater)**

HIGH ALERT - SPECIFIC MEDICATIONS

Based on the medication error reports submitted to the Medication Error Reporting System (MERS), a list of potential high alert medications **(Table 2)** has been identified as high-risk medications that could cause harmful incidents. These medications require special safeguards to reduce the risk of errors and ensure patient safety. All healthcare professionals involved in their use will treat them with special attention and follow the established requirement. Data analysis from MERS in 2019, demonstrated the most commonly reported high alert medications were insulin, enoxaparin, warfarin, fondaparinux, and heparin. In comparison, the Institute for Safe Medication Practices (ISMP) has identified insulin, opiates and narcotics, injectable potassium chloride (or) phosphate concentrate, intravenous anticoagulants (heparin), and sodium chloride solutions above 0.9% as the top five (5) high alert medications.

Special precautions and error prevention strategies as recommend in **Table 2** will serve as useful initiatives for system improvement to avoid harmful injury with identified high alert medications in healthcare facilities.

Table 2: List of Potential High Alert Medications

No.	Medication name	Common type of errors	Common risk factors	Recommendation of improvement strategies
1.	**Potassium chloride (KCl) injection**	• Incorrect drug • Drug preparation error	• Potassium Chloride injection and Dextrose 50% were stored next to each other in the medication shelf • Incorrect preparation of medication	a) Develop a clear guideline/standard operating procedure/protocol for the use of KCl injection and ensure that it is readily available and accessible in all patient care units. b) Ensure complete prescribing information for KCl injection which specify the total dose, route, volume of dilution, rate of infusion etc. e.g. 0.5 gram in 50ml NS over 1 hour. c) Perform independent countercheck before preparation, dispensing and administration-at least two healthcare personnel should check the correct product, dose, dilution, labelling, route and rate as per safety protocol. d) Add cautionary label. **CAUTION** CONCENTRATED KCl FATAL IF INJECTED UNDILUTED HIGH CONCENTRATED ELECTROLYTE DILUTE BEFORE IV ADMINISTRATION

No.	Medication name	Common type of errors	Common risk factors	Recommendation of improvement strategies
				e) Choose a designated area/container for storage.
2.	**Lignocaine HCl (Lidocaine HCl) Injection**	• Incorrect drug • Incorrect route of administration	• Confusion of different strength/ multiple formulation • Confusion of different route of administration (e.g. IV vs IM) • Confusion of different indication • Confusion of medication preparation	a) Keep an up-to-date list of all available lignocaine HCl formulation • generic name • trade name • available strengths b) Different brand of products has different reconstitution/dilution and administration instructions. • Ensure appropriate medication preparation, dilution, dosage and rate of administration of the medication. c) Read the labels/package insert before preparing the reconstitution/dilution. d) All practitioners responsible for administering medications should be trained on administrations and resuscitation procedures. e) Perform independent countercheck • dosing • infusion pump programming • concentration • dilution f) Add auxiliary label when appropriate • To improve readability of labels e.g. if the preparation is not for IV use, **NOT FOR IV USE** If the preparation is for IM use only, **FOR IM USE ONLY**
3.	**Insulin**	• Incorrect dose • Incorrect type of insulin/ brand	• Look alike sound alike medication (i.e. mixtard vs insulatard, Insugen N vs Insugen R)	a) Keep an up-to-date list of all available insulin and the injection device in the facility. b) Limit the variability of insulin in the facility. c) Perform an independent countercheck before dispensing and administering insulin. d) Spell out the word “units” instead of “U”.

No.	Medication name	Common type of errors	Common risk factors	Recommendation of improvement strategies
		• Incorrect injecting device (brand variation) given to patient	• Availability of multiple brands of insulin • Use of the abbreviation "U" for units mistaken with "0" • Storage of insulin medications next to each other	e) Add cautionary label to differentiate the type of insulin.
4.	**Enoxaparin and Fondaparinux**	• Incorrect dose • Incorrect frequency • Prescribe/ supply fondaparinux instead of enoxaparin	• Confusion with dosing regimen • Dosage prescribed is not based on patient's weight • Inaccurate renal dose adjustment • Look alike packaging (40mg vs 60mg) • Look alike medication (enoxaparin vs fondaparinux)	a) Develop a clear guideline/standard operating procedure/protocol for the use of these medications and ensure that they are readily available and accessible in all patient care units. b) Keep an up-to-date list of all available strengths of these medications in the facility. c) Standardize concentration/strength of available anticoagulants. d) Standardize the baseline information, such as weight in kilograms and renal function, needed during the ordering of anticoagulants. e) Use Tall-man lettering and store look alike medications separately. f) The medication, dose and route of administration should be independently counterchecked by another healthcare personnel before administration. g) Emphasize on patient counseling/ education. h) Be diligent in anticoagulants calculations. i) Using auxiliary labels or cautionary label.
5.	**Warfarin**	• Incorrect dose/ frequency/ duration • Incorrect labelling dose	• Complexity of dosing regimen and monitoring • Look alike medication/ packaging • Availability of multiple strength	
6.	**Heparin**	• Incorrect dose/ frequency • Confusion in drug preparation	• Complexity of dosing regimen and monitoring • Look alike medication • Availability of multiple strength • Unclear, imprecise concentration	

No.	Medication name	Common type of errors	Common risk factors	Recommendation of improvement strategies
			and total volume information on container label	
7.	**Chloral hydrate mixture**	• Incorrect dose • Incorrect route of administration	• Prescribe/ administer incorrect dose due to inaccurate body weight or incorrect calculation • Supply incorrect strength • Administer intravenously instead of orally	a) Clearly label the medication: **"FOR ORAL USE ONLY"** b) Use of oral syringe may help to reduce incorrect route of administration of an oral medication into a vein. c) The medication, dose and route of administration should be independently counterchecked by another healthcare personnel before administration. d) Should only be given by healthcare personnel, not by patient/caregiver unless under special supervision.
8.	**Noradrenaline**	• Incorrect infusion rate • Incorrect dose • Incorrect drug	• Inexperienced personnel • Inadequate knowledge on noradrenaline/ adrenaline calculation • Inaccurate dose prescribed (e.g. 0.2mcg/hour instead of 0.2mcg/kg/min) • Look alike sound alike medication (i.e. Noradrenaline vs Adrenaline)	a) All personnel shall be trained prior to handling noradrenaline/adrenaline injection. b) Prescribers must have proficient knowledge on the dose and potential side effects. c) Specify the dose, route and rate of infusion on the prescription. d) The correct medication, dose, route and rate of infusion should be independently counterchecked by another healthcare personnel prior to administration. e) Using auxiliary labels or cautionary label.
9.	**Adrenaline**	• Incorrect dose • Incorrect drug		

COMMON RISK FACTORS

Common risk factors associated with high alert medications are as follows: -

Different route of administration

Confusion between IM, IV, Intrathecal, epidural preparations

Wrong infusion rate

- Wrongly prescribed or miscalculation of infusion rate
- An incorrect infusion rate may be programmed on the infusion pump

Incorrect preparation of drug

- Incorrect dilution
- Incorrect diluent
- Incorrect dose/strength of drug
- Incorrect calculations

Look Alike Sound Alike (LASA)

Look alike or sound alike product and similar packaging

Misinterpretation of medications order

- Use of the abbreviation "U" for units mistaken with "0" and result in 10-fold overdose
- Use trailing zeros result in 10-fold overdose

Availability of products variation

Confusion of different strengths/multiples formulations/brands/ colours of the same drug

Ambiguous labelling

Unclear concentration and total volume information on the container/syringe label

ASSESSMENT QUESTIONS GUIDE TO IDENTIFY RISK FACTORS OF POTENTIAL ERRORS OF HIGH ALERT MEDICATIONS IN THE HEALTHCARE FACILITIES

- Which medication have been reported with serious error in your facility?
- Does this medication treat a high-risk patient (e.g. neonates, critical care, elderly)?
- Are there multiple formulations?
- Should there be a limited concentration available?
- Does the medication match the indication?
- Should there be maximum dose limits?
- Are weight-based dose limits needed?
- Is the route of administration considered high risk?
- Should there be a limit or maximum infusion rates?
- Is an independent countercheck recommended?
- Does the medication require credentialed personnel for administration?
- Is special monitoring required?
- Are auxiliary warning labels required?

SAFE HANDLING OF HIGH ALERT MEDICATION

MANAGEMENT OF HIGH ALERT MEDICATIONS

- List of high alert medications used within the facility shall be identified.
- List of high alert medications shall be disseminated to all healthcare personnel in the facility.
- High alert medications should have **HIGH ALERT MEDICATION** labels on storage shelves, containers, product packages **OR** loose vials/ampoules.
- Use either HAM sticker/label or HAM envelope.
- Any changes of brand/colour/preparation of high alert medications must be informed to the users as soon as possible.
- Medications identified as high alert shall be targeted for specific error prevention strategies.
- Review and evaluate the checklist for high alert medications in Medication Safety Self – Assessment Form.
- High alert medications will be prescribed, dispensed, and administered using practices that are proven safe.
- High alert medication must be counterchecked before they are prepared, dispensed and administered to the patients.
- A system shall be established whereby one healthcare professional prepares the medication and another person counterchecks it.
- All high alert medications issued from the pharmacy must be counterchecked and verified by another pharmacy staff prior to dispensing for the purpose of medication safety and accuracy.
- All equipment or devices used in the preparation and/or administration of medications shall be calibrated and maintained according to Standard Operating Procedure (SOP).
- Utilize engineering safety controls when appropriate. i.e. use of oral syringe for liquid (oral) medications, computerized system.
- Identify and keep apart look alike sound alike of high alert medications.
- Monitor and report adverse drug reaction and medication error related to high alert medications.

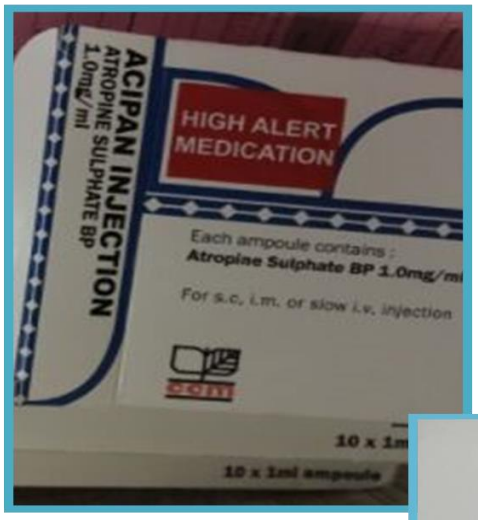
- Apply and practice **three main principles** to safeguard the use of high alert medications: -

1.	**Reduce or eliminate the possibility of error**
	▪ Limit the number of high alert medications on the hospital/health clinic drug formulary ▪ Limit the concentration/strength of medication available
2.	**Make errors visible**
	▪ Having two individuals to countercheck on the medications, calculations, preparations, administration etc. ▪ Practice 5 Rights - Know Your Medicines ▪ (Right patient, Right medication, Right dose, Right route, Right time) ▪ "Know, Check, Ask" before giving medication to the patient
3.	**Minimize the consequences of error**
	Stock high alert medications in smaller volume/unit

LABELLING OF HIGH ALERT MEDICATIONS

High Alert Medications should have **HIGH ALERT MEDICATION** labels on:

PRODUCT PACKAGES



CONTAINERS

HAM ENVELOPE

STORAGE SHELVES

LOOSE VIALS/ AMPOULES

MEDICATION MANAGEMENT PROCESS: ERROR PREVENTION STRATEGIES TO IMPROVE THE SAFETY OF HIGH ALERT MEDICATIONS

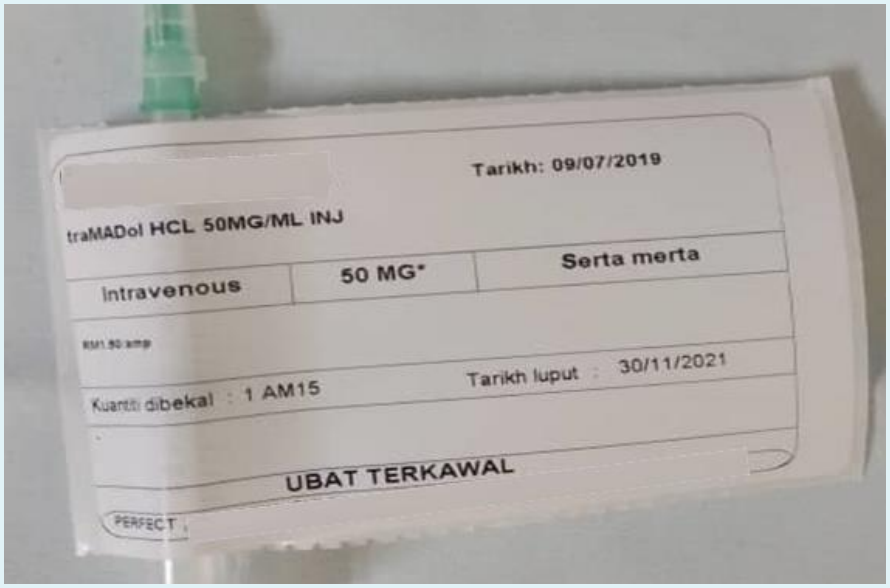
Procurement	
1.	Limit the medication strengths available in the formulary of each healthcare facility.
2.	Avoid frequent changes of brand or colour. Notify the end users whenever there are changes.
3.	Encourage the purchase of equipment and consumables with safety features for safe medication administration. i.e. oral syringes; pumps with locking mechanism.
Storage	
1.	Use cautionary label/label enhancement on packages and storage bins of identified high alert medication. Example: High Alert Medications should have **HIGH ALERT MEDICATION** labels on storage shelves, containers, product packages or loose vials/ampoules. Ensure the **HIGH ALERT MEDICATION** label did not cover the information written on the product's label.
2.	All high alert medications should be kept in individual labeled containers. Avoid look-alike and sound-alike medications or different strengths of the same medication from being stored side by side.
3.	Use TALL-man lettering to emphasize differences in medication names (eg. DOPamine and DOBUTamine).
4.	Limit the ward's floor stock medications to the standard requirement. Reduce the quantity and variation of strength/preparation stocked.
5.	All personnel must read the **HIGH ALERT MEDICATION** labels carefully before storing to ensure medications are kept at the correct place.
Prescribing	
1.	Use standardized forms for written orders of cytotoxic medications and parenteral nutrition.
2.	Do not use abbreviation and acronym.

3.	Specify clearly the dose, route and rate of infusion for high alert medication prescribed.
4.	Prescribe oral liquid medications with the dose specified in milligrams.
5.	Use leading zero (e.g. 0.5mg instead of .5mg).
6.	Do not use trailing zero (e.g. 5.0 mg can be mistaken as 50 mg).
7.	Use generic names instead of the medication's brand name.
8.	Always take note of body weight and body surface area for specific medications (e.g. chemotherapy and paediatric patients).
9.	• Verbal communication of medication order on high alert medication are **NOT RECOMMENDED** except in emergency or urgent situations only. • When verbal order must be taken, the personnel receiving the order must verbally repeat the order back to the prescriber for verification. • Verbal orders should be immediately documented in the patient's medical record, reviewed, and countersigned by the prescriber in accordance with organizational policy.
Preparation	
1.	Establish a counterchecking system for all preparations involving high alert medication.
2.	The calculations involving: • cytotoxic medications and parenteral nutrition shall be **independently counterchecked** by another personnel. • extemporaneous preparations shall be **independently counterchecked** by another personnel.
3.	All diluted medications **MUST BE LABELED** with the **name and strength** immediately upon dilution. Example of label:

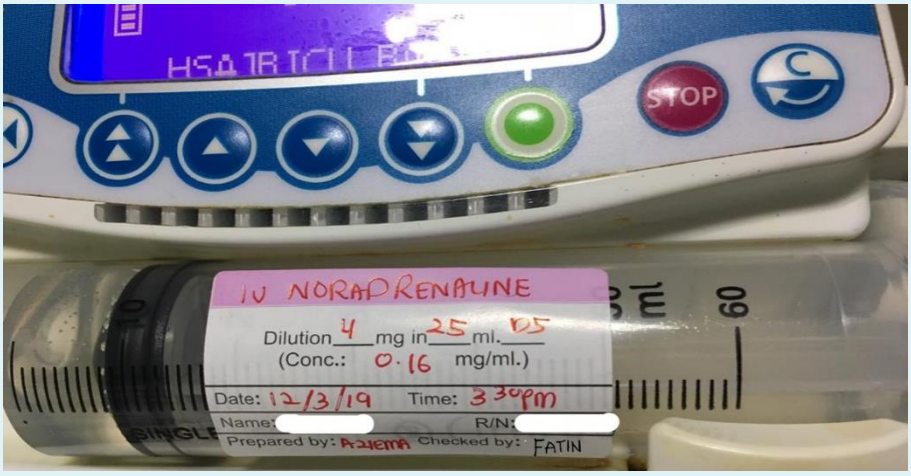
DRUG: CONCENTRATION: ____ mg in ____ mL NS/D5/____	
DATE:	TIME:
PATIENT'S NAME: R/N:	
PREPARED BY:	CHECKED BY:

a) Pharmacy based-iv admixture

b) Ward based-prepared in ward



c) Infusion pump



Dispensing	
1.	All high alert medication containers, product packages or loose vials/ampoules issued to wards/units must be labeled as **HIGH ALERT MEDICATION**. Note: HAM labeling on pre-pack tablet/capsule for "unit of dose" supply in the medication trolley is not mandatory. However, initiatives must be taken by facilities to increase awareness amongst healthcare professionals on the importance of counter checking when handling HAMs.
2.	High alert medications to be dispensed to patients need not be labeled as high alert.
3.	High alert medications must be **counterchecked** before dispensing.
4.	High alert medications shall be checked upon receiving by the healthcare professionals.
Administration	
1.	The following particulars shall be independently counterchecked against the prescription or medication chart at the bedside by two appropriate persons before administration: • Patient's identification - patient's name and RN • Name, dose and strength of medications • Route and rate (pump setting and line placements when necessary) • Expiry date • Line attachments
2.	Label the distal ends of all access lines to distinguish IV from epidural lines.
3.	Ensure no distraction during the administration of medications to patients by implementing special measures (Example: wearing special vest).
4.	Return all unused or remaining specially formulated preparations to the pharmacy when no longer required.
5.	Ensure administration of intrathecal, cytotoxic medications, epidural analgesics and parenteral nutrition is done by trained personnel.

Monitoring	
1.	Closely monitor and document vital signs, laboratory data, patient's response before and after administration of high alert medications.
2.	Keep antidotes and resuscitation equipment in wards/emergency room/units.
Documentation	
1.	Ensure complete documentation on the medication record.
2.	Always verify any unclear or inaccurate documentation prior to dispensing or administering medications.
Medication Information	
1.	List of high alert medications used within the facility shall be identified.
2.	List of high alert medications shall be disseminated to all healthcare personnel in the facility.
3.	Updated references or dilution guide should be made available in the wards, treatment room and pharmacy.
4.	Monitor and report adverse drug reactions and medication errors related to high alert medications.
Training of Healthcare Professional	
1.	All healthcare personnel shall be trained in safe handling of high alert medications and emphasize on the importance of counterchecking to prevent potential errors and enable them to respond promptly when mistakes do occur.
Patient Education	
1.	Educate patient and family members/caregivers on: - • 5 Rights(5R) - Know Your Medicines (Right patient, Right medication, Right dose, Right route, Right time) • Common side effects/potential adverse event • Adherence to medication regimens

APPENDIX 1

Examples of HIGH ALERT MEDICATION label

Healthcare facilities may determine the appropriate size of the high alert medication labels to be used whether on the product, container, storage shelves or loose vials/ampoules.

APPENDIX 2

Examples on proper use of HIGH ALERT MEDICATION label on ampoule/vial

i. Ampoule

ii. Vial

Ensure the HIGH ALERT MEDICATION label did not cover the information written on the product's label.

APPENDIX 3

MEDICATION SAFETY SELF ASSESSMENT FORM: PART D - HIGH ALERT MEDICATIONS (PF 11.6)

Part	Question	Score
D	**HIGH ALERT MEDICATIONS (HAMs)** Safe handling of High Alert Medications.	
15	High alert medications used within the facility have been identified.	
16	List of high alert medications has been disseminated to all healthcare personnel in the facility.	
17	Cautionary label/label enhancement is used on packages and storage bins of identified high alert medications.	
18	Both the medication and dose of high alert medications must be independently counterchecked by another healthcare personnel and documented before administration.	

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